



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/549,852

09/23/2005

Hans-Peter Buchstaller

24945-0023

7098

49442 7590 06/17/2008
BAKER & DANIELS LLP
805 15TH STREET, NW, SUITE 700
WASHINGTON, DC 20005

EXAMINER

CHU, YONG LIANG

ART UNIT

PAPER NUMBER

1626

MAIL DATE

DELIVERY MODE

06/17/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/549,852	Applicant(s) BUCHSTALLER ET AL.	
	Examiner YONG CHU	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 March 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) 1-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 33-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>03/12/2008</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 03/11/2008 has been entered. Upon entering the submission, claims 1-37 are currently pending in the instant application, Claims 1-32 remain withdrawn as non-elected subject matter. Claims 33-37 are under examination on the merits.

Information Disclosure Statement

Applicants' Information Disclosure Statement, filed 03/11/2008 has been considered. Please refer to Applicant's copy of the PTO-1449 submitted herewith.

Response to RCE Submission

Rejection under 35 U.S.C. §112, second paragraph

Applicants' argument on the ground that claim 33 does not contain the rejected term "pyridinyl derivative", has been considered and is found persuasive. However, the rejected term should be "pyridinyl residue", instead, which still renders claim 33 indefinite. Since applicants have amended the claim, and the rejection is overcome by the amendment. Therefore, the rejection has been withdrawn.

Rejection of claim 33 under 35 U.S.C. §102(b)

Applicants' amendment has obviated the rejection of claim 33 under 35 U.S.C. §102(b).

Obviousness-type Double Patenting Rejection

Since applicants' do not respond to this rejection, and the instantly examined claims are not ready for allowance, this rejection is maintained.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 33-37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claims 33-37 are rejected due to claiming a **"solvate"** of a compound of the Formula (II) according to claims 33-37. The instant specification defines the general term "solvate" at paragraph [0116] as a complex of variable stoichiometry formed by a solute, but does not specifically define the compounds which can form a solvate of the compounds. According to Vipagunta et al., *Advanced Drug Delivery Reviews*, page 1, a **solvate** exist as crystalline forms. They are specific crystalline forms of a compound that can crystallize in different forms, and not all compounds can form crystalline. The specification does not reasonably provide enablement for forming

Art Unit: 1626

crystalline of each of the compound list in the claims. Because of high level of unpredictability associated with crystalline of the compounds, a greater amount of evidentiary support is needed to fully satisfy the requirement of 35 U.S.C 112, first paragraph. It is noted that crystallization art is unpredictable, requiring each embodiment to be individually assessed for the possibility.

A disclosure should contain representative examples, which provide reasonable assurance to one skilled in the art that compounds fall within the scope of a claim will possess the crystalline form of the compound. To practice the claimed invention herein, a person of skill in the art would have to engage in undue experimentation to test which compounds would form crystalline, with no assurance of success.

Claims 33-37 are also rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. According to Vippagunta et al., *Advanced Drug Delivery Reviews*, page 1, a “solvate” exists as crystalline forms with the specific orientation with the specific compound. However, such “solvate” is not described in the specification to reasonably convey one skilled in the art. There is even not a single working example on solvate disclosed in the specification in terms of a complex of variable stoichiometry formed by a solute, and the crystal forms of the compounds.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

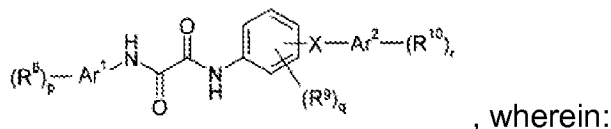
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 33-37 are rejected under 35 U.S.C. 102 (b) as being anticipated by Boger et al., *U.S. Patent No. 4,656,183* (the '183 patent).

Applicants' claims relate to a compound of Formula (II)



Ar^1 is selected from the group consisting of aromatic hydrocarbons containing 6 to 14 carbon atoms;

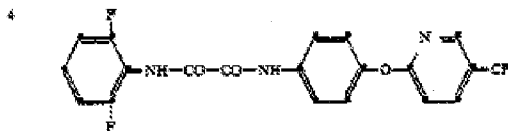
Ar^2 is pyridinyl bonded to X in the 3- or 4- position relative to the pyridinyl N;

X is $-O-$;

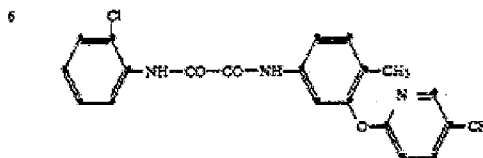
Art Unit: 1626

 R^8 is H, Hal, and $C(Hal)_3$; R^9 is H or alkyl; R^{10} is H, Hal, and $C(Hal)_3$; p, r is independently from one another 0,1,2,3,4 or 5; q is independently from one another 0,1,2,3, or 4, and**Hal** is F, Cl, or Br, or pharmaceutically acceptable salts thereof.

The '183 patent discloses the compound 4



, compound 6 (CAS RN 98499-96-8)

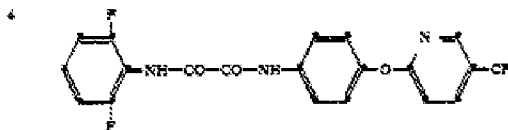


in columns 11-

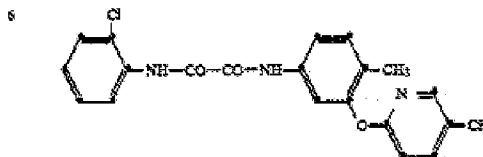
12, and the other compounds listed in columns 9-28. These compounds are used as pesticides.

Determination of the scope and content of the prior art (MPEP §2141.01)

The '183 patent discloses the compound 4



, compound 6 (CAS RN 98499-96-8)



in columns 11-

12, and the other compounds listed in columns 9-28. These compounds are used as pesticides.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the '183 patent and the instantly claimed compounds, is that the prior art teaches the compounds having **Ar²** is pyridinyl bonded to **X** in the 2-position relative to the pyridinyl N, while the instantly claimed compounds having **Ar²** is pyridinyl bonded to **X** in the 3-, or 4- position relative to the pyridinyl N.

Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)

To those ordinary skilled in the art, the instantly claimed invention would have been obvious over the '183 patent, because the prior art compounds and the instantly claimed compounds differ only in the placement of substituents in a ring system. Compounds which differ only in the placement of substituents in a ring system is not unobvious absent unexpected results. In re Jones, 162 F.2d 638, 74 USPQ 152 (CCPA 1947). The motivation to make the claimed compounds derives from the expectation that knowing properties of one member of series compounds would in general know what to expect in adjacent members as medicine or pesticide. Therefore, the instant claimed compounds would have been suggested to one skilled in the art. The Office has established *prima facie* obviousness case, and the burden of coming forward with evidence or arguments shifts to the applicant who may submit additional evidence of nonobviousness, such as comparative test data showing that the claimed invention possesses improved properties not expected by the prior art (e.g. unexpected results).

Conclusion

- Claims 33-37 are rejected.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Chu whose telephone number is 571-272-5759. The examiner can normally be reached between 7:00 am - 3:30 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Status Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Yong Chu, Ph.D./
Patent Examiner
Art Unit 1626